Mathiowitz, et al. U.S.S.N. 10/663,265

Upon entry of this Amendment, the following listing of claims replace prior versions and listings of claims in the application.

Please cancel claims 1-2. Please add new claims 3-18.

Please replace the pending claims with the following listing of claims:

Listing of Claims:

1.-2. (Cancelled)

- 3. (New) A system for delivery of naked DNA to a tissue site of a mammalian subject, the system comprising a polymeric matrix and an effective amount of naked DNA dispersed within the polymeric matrix, the polymeric matrix being dissolvable in a volatile organic solvent, wherein said polymeric matrix is selected from the group consisting of synthetic polymers, synthetically polymerized polysaccharides, synthetically polymerized proteins, chemically synthesized polymers, chemically synthesized polysaccharides, and chemically synthesized proteins, wherein
 - a) wherein the DNA contains a gene operatively linked to a promoter, the nucleotide sequence of said gene being greater than 30 nucleotides in length;
 - b) the polymeric matrix is in a form selected from the group consisting of stents, coatings, slabs, and films; and
 - c) wherein the naked DNA is released or diffuses from the polymeric matrix.
- 4. (New) The system of claim 3, wherein said system can be implanted into a mammal.
- 5. (New) The system of claim 3, wherein the polymeric matrix comprises a polymer selected from the group consisting of polymers of lactic acid and glycolic acid, polyanhydrides, poly(ortho)esters, and poly(caprolactone).
- 6. (New) The system of claim 3, wherein the polymeric matrix is biodegradable.
- 7. (New) The system of claim 3, wherein the polymeric matrix is non-biodegradable.

Mathiowitz, et al. U.S.S.N. 10/663,265

- 8. (New) The system of claim 3, wherein the polymeric matrix contains sufficient naked DNA such that the naked DNA can be released from said system for at least three months.
- 9. (New) The system of claim 3, wherein approximately 0.1-90% by weight of naked DNA is loaded into the polymeric matrix.
- 10. (New) The system of claim 3, wherein the naked DNA comprises supercoiled DNA, circular DNA, or a combination thereof.
- 11. (New) The system of claim 3, wherein the naked DNA is greater than 100 nucleotides in length.
- 12. (New) The system of claim 3, wherein the polymeric matrix is bioadhesive.
- 13. (New) The system of claim 3, wherein the system further comprises compounds inhibiting inflammation due to the polymeric matrix, compounds increasing inflammation due to the polymeric matrix, antiinflammatories, or inhibitors of cytokines.
- 14. (New) The system of claim 3, wherein the effective amount of naked DNA dispersed within the polymeric matrix is greater than 20 µg.
- 15. (New) A method for delivery of naked DNA to a tissue site of a mammalian subject, the method comprising implanting the system of claim 4 into the mammalian subject and allowing the naked DNA to be released from or to diffuse from the polymeric matrix.
- 16. (New) The method of claim 15, wherein the polymeric matrix is formed prior to implantation into the mammalian subject.

- 17. (New) The method of claim 15, wherein the polymeric matrix is formed after implantation into the mammalian subject.
- 18. (New) A system for delivery of naked DNA to a tissue site of a mammalian subject, the system comprising a polymeric matrix and an effective amount of naked DNA dispersed within the polymeric matrix, the polymeric matrix being dissolvable in a volatile organic solvent, wherein
 - a) the effective amount of naked DNA dispersed within the polymeric matrix is greater than 20 µg and wherein the DNA contains a gene operatively linked to a promoter, the nucleotide sequence of said gene being greater than 30 nucleotides in length;
 - b) the polymeric matrix is in a form selected from the group consisting of stents, coatings, slabs, and films; and
 - c) wherein the naked DNA is released or diffuses from the polymeric matrix.